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10/541,501

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EXAMINER

WESSENDORF, TERESA D

ART UNIT

PAPER NUMBER

1639

MAIL DATE

DELIVERY MODE

11/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/541,501

Applicant(s)

ST. HILAIRE ET AL.

Examiner

T. D. Wessendorf

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4,6,7,16,22,26,29-31,35,36,43,44,46,49,50,77,78 and 88-90 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43, 88 and 90 is/are rejected.
- 7) ☒ Claim(s) 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 3,4,6,7,16,22,26,29-31,35,36,46,49,50,77,78,89 and 90.

DETAILED ACTION

Election/Restrictions

Applicant's election with (partial) traverse of VIII (claims 43, 88) is acknowledged. The traversal is on the ground(s) that it appears that the compounds of groups VII (43, 88, 90) and IX (43-44, 88) are within the scope of group VIII, and consequently groups VII and IX should be rejoined with elected group VIII. If such rejoinder is granted, then claims 43, 44, 88 and 90 will be examined.

Upon reconsideration of the restriction requirement and applicants' request and traversal, groups VII (43, 88, 90) and IX (43-44, 88) would be rejoin with the elected invention, group VIII (claims 43 and 88).

In response to the species restriction, applicants elect the compound HY6, which is shown in claim 44. HY6 is clearly within the scope of elected claim 43. Applicants traverse the species restriction on the ground that a generic claim covering said species is allowable. This is not found persuasive because the claimed generic compound has not been found allowable. Thus, since each species is structurally different hence, the species restriction is proper.

Claims 43, 44 and 90 (with respect to the non-elected species), are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement.

Status of Claims

Claims 3-4, 6-7, 16, 22, 26, 29-31, 35-36, 43, 44, 46, 49-50, 77-78 and 88-90 are pending

Claims 3-4, 6-7, 16, 22, 26, 29-31, 35-36, 43-44, 46, 49-50, 77-78 and 89-90 (with respect to the non-elected species) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species.

Claims 43, 44 (with respect to the elected species) and 88 are under examination.

Specification

The abstract of the disclosure is objected to because it uses the abstract of the PCT and the abstract is not on a separate sheet. Correction is required. See MPEP § 608.01(b).

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, grammatical and idiomatic). Applicant's

Art Unit: 1639

cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "dotted lines indicates an optional carbonyl" is not positively recited in the specification. The specification appears to show said dotted lines to be the stereochemistry of the compound.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43 and 90, as amended and added, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New Matter Rejection

Claim 43 which recites wherein the "ligand according to claim 88" is of formula IV is not supported in the as-filed specification. Newly added claim 88 recites a ligand or an isolated ligand-protein binding pair identified by the process according to claim 3. However, claim 43 with its numerous different substituents and broad definitions for the R variables do not seem to have been identified. (This formula seems to read on a library of ligand, not to an identified ligand). MPEP 714.02 states that applicants specifically point out where in the specification support for the new claimed limitation(s) can be found.

Claim Rejections - 35 USC § 112

Claims 88, 43 and 90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 88 is unclear as to whether an isolated ligand or a library of ligand is intended. This claim depends on the process claim 3, which recites a ligand library and an identified ligand.

Art Unit: 1639

2. Claim 43 is indefinite in the recitation that "dotted lines indicates an optional carbonyl", especially in the absence of positive recitation in the specification.

4. The metes and bounds of the claimed "unnatural amino acid" within the claimed context are not definitely recited in the specification. It does not define the manner as to the kind of atoms or moieties, arrangement and other qualifying features that differentiates one unnatural amino acids from another or from the prior art. Claim 43.

5. Claim 90 reference to the different Tables e.g., 1-3 is indefinite. MPEP 2173.05(s) states that where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1639

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 88 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over St. Hilaire et al (Journal of the American Chemical Society (1998), 120(51), 13312-13320). (Based on the claimed isolated ligand).

Art Unit: 1639

St. Hilaire et al discloses at e.g., page 13312, abstract:

Glycopeptides that mimic the action of oligosaccharides have been rapidly identified through the implementation of combinatorial library methodology combined with a novel, easy, screening and anal. method. A glycopeptide library containing three different glycosyl amino building blocks, Fmoc-Asn(β -Ac3GlcNAc)-OPfp (Fmoc = 9-fluorenylmethoxycarbonyl; Pfp = pentafluorophenyl), Fmoc-Thr(α -Ac4Man)-OPfp, and Fmoc-Thr(α -Ac4Man(1 \rightarrow 3) α -2-O-Bz-4,6-Ac2Man)-OPfp, was synthesized by the portion-mixing method on PEGA solid support. The library was designed to facilitate rapid and unambiguous analysis of the active glycopeptides detected during the high throughput-screening step. Consequently, the library was synthesized using the ladder synthesis approach and linked to the solid support via a photolabile linker. The glycosyl amino acids were labeled with carboxylic acid tags to allow unambiguous identification of the glycan moiety. Photolytic release of active glycopeptide from the resin was induced by irradiation of the bead with the MALDI-TOF-MS laser, and anal. of the resulting spectrum presenting the ladder of glycopeptide fragments yielded the sequence of the active glycopeptide. Glycopeptide ligands were identified for the C-type lectin from *Lathyrus odoratus* by screening the fluorescent-labeled protein in a solid-phase binding assay of the PEGA resin-bound glycopeptide library. Of the several glycopeptide ligands detected, most contained Man or GlcNAc, glycans that display specificity for the lectin in hemagglutination assays.

Claim 88 drawn broadly to a ligand identified by the process according to claim 3 is anticipated or obvious over the specific ligand disclosed by St. Hilaire. The ligand disclosed by St. Hilaire is the same or similar to the claimed ligand except for the process by which it is made.

MPEP § 2113, states: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695,698, 227 USPQ 964, 966 (Fed. Cir. 1985)." When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either 35 U.S.C. 102 or

Art Unit: 1639

35 U.S.C. 103 is eminently fair and acceptable. PTO is not equipped to make and then compare products. In re Brown, 459 F.2d 531, 173 USPQ 685 (CCPA 1972).

Claim 88 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lohse (6602685).

Lohse discloses throughout the patent and at e.g., col. 6, line 25 up to col.7, line 33:

.....compound-protein pairs (for example, small molecule-protein pairs) may be isolated and identified on beads.....

Claim 88 drawn broadly to a ligand identified by the process according to claim 3 is anticipated or obvious over the ligand-protein pair disclosed by Lohse. The ligand-protein pair disclosed by Loshe is the same or similar to the claimed ligand except for the process by which it is made.

MPEP § 2113, states: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)." When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either 35 U.S.C. 102 or 35 U.S.C. 103 is eminently fair and acceptable. PTO is not

Art Unit: 1639

equipped to make and then compare products. In re Brown, 459 F.2d 531,173 USPQ 685 (CCPA 1972).

Claim 88 is rejected under 35 U.S.C. 102(a, e) as being anticipated by Tomlinson et al., US 20020115068.

Tomlinson et al., throughout the publication and abstract, teach, for example, a process for screening a repertoire of molecules, such as a proteome (Tomlinson et al., at para [0095]) or a combination of a repertoire of antibody heavy chains with a repertoire of light chains, and screening the heavy chain and light chains against one or more target ligands, reading on identifying specific members of a previously unknown protein-ligand binding pair; and at para [0144]); teach constructing repertoires for screening, that include small organic molecules synthesized by the methods of combinatorial chemistry, and contemplate the synthesis of such molecules onto polystyrene, polycarbonate or other plastic polymer beads (see para [0104], para [0144] and para [0148]), thereby reading on synthesizing a ligand library onto resin beads to form an immobilized ligand library, and wherein each bead of the immobilized library comprises one member of the ligand library, (see para [0216], teaching creation of chemical libraries by parallel synthesis and split and pool approaches); (b) incubating the immobilized ligand library with one or two or more protein mixture (see the

Art Unit: 1639

abstract and para [0238]-[0240]); including human proteins (Tomlinson at para [0005], [0176], [0177], [0180], [0181], [0193], and [0198]); and wherein the protein is tagged with a genetic label that includes FLAG tag (Tomlinson at para [0212]); (c) detecting an immobilized ligand-protein binding pair from the incubation mixture (see para [0238]- [0240]) and wherein detection is by immunoassay (Tomlinson at para [0045]); (c) identifying the ligand of the ligand-binding pair (see, e.g., Tomlinson at claim 30); and (d) identifying the protein of the ligand-binding pair, (see, e.g., Tomlinson at claim 30); wherein the identified ligand and protein are specific members of a previously unknown ligand-protein binding pair (Tomlinson at para [0142]).

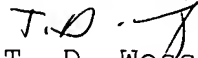
Claim 44 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571) 272-0765. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Art Unit: 1639

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw

November 5, 2007

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